

prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions that are obtained from commercial manufacturers and are properly labeled as to content and concentration. Calibrators and controls may not be prepared from the same stock solution. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and when scheduled for expiration.

**§ 26.168 Blind performance testing.**

(a) Each licensee and other entity shall submit blind performance test samples to the HHS-certified laboratory.

(1) During the initial 90-day period of any contract with an HHS-certified laboratory (not including rewritten or renewed contracts), each licensee or other entity shall submit blind performance test samples to each HHS-certified laboratory with whom it contracts in the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 100 blind performance specimens) or 30 blind performance test samples, whichever is greater.

(2) Following the initial 90-day period, the number of blind performance test samples submitted per quarter must be a minimum of one percent of all specimens (up to a maximum of 100) or ten blind performance test samples, whichever is greater.

(3) Both during the initial 90-day period and quarterly thereafter, licensees and other entities should attempt to submit blind performance test samples at a frequency that corresponds to the submission frequency for other specimens.

(b) Approximately 60 percent of the blind performance test samples submitted to the laboratory must be positive for one or more drugs or drug metabolites per sample and submitted so that all of the drugs for which the FFD program is testing are included at least once each calendar quarter, except as follows:

(1) Licensees and other entities shall submit blind performance test samples that are positive for marijuana me-

tabolite at least two times each quarter; and

(2) In at least two quarters each year, licensees and other entities shall submit an additional blind performance test sample that is positive for cocaine instead of the required sample that is positive for PCP.

(c) The positive blind performance test samples must be positive for only those drugs for which the FFD program is testing and formulated at concentrations established in paragraph (g)(2) of this section.

(d) To challenge the HHS-certified laboratory's ability to limit false negatives, approximately 10 percent of the blind performance test samples submitted to the laboratory each quarter must be formulated at the concentrations established in paragraph (g)(3) of this section.

(e) To challenge the HHS-certified laboratory's ability to determine specimen validity, the licensee or other entity shall submit blind samples each quarter that are appropriately adulterated, diluted, or substituted, in the amount of 20 percent of the specimens submitted that quarter or at least three samples per quarter (one each that is adulterated, diluted, or substituted), whichever is greater. These samples must be formulated at the concentrations established in paragraphs (g)(4) through (g)(6) of this section.

(f) Approximately 10 percent of the blind performance test samples submitted to the laboratory each quarter must be negative, as specified in paragraph (g)(1) of this section.

(g) Licensees and other entities shall use only blind performance test samples that have been certified by the supplier to be—

(1) Negative. A negative blind performance test sample may not contain a measurable amount of a target drug analyte and must be certified by immunoassay and confirmatory testing;

(2) Drug positive. These samples must contain a measurable amount of the target drug or analyte in concentrations ranging between 150 and 200 percent of the initial cutoff values and be certified by immunoassay and confirmatory testing to contain one or more drug(s) or drug metabolite(s);

(3) A false negative challenge. This blind performance test sample must contain a measurable amount of the target drug or analyte in concentrations ranging between 130 and 155 percent of the initial cutoff values;

(4) Adulterated. The adulterated blind performance test sample must have a pH of less than or equal to 2, or greater than or equal to 12, or a nitrite or other oxidant concentration equal to or greater than 500 mcg/mL, equal to or greater than 50 mcg/mL chromium (VI)-equivalents, or a halogen concentration equal to or greater than the LOD. Blind performance test samples for other adulterants must have adulterant concentrations equal to or greater than (or equal to or less than, as appropriate) the initial cutoff levels used by the licensee's or other entity's HHS-certified laboratory;

(5) Dilute. The dilute blind performance test sample must contain a creatinine concentration that is equal to or greater than 5 mg/dL but less than 20 mg/dL, and the specific gravity must be greater than 1.0010 but less than 1.0030; or

(6) Substituted. The substituted blind performance test sample must contain less than 2 mg/dL of creatinine, and the specific gravity must be less than or equal to 1.0010, or equal to or greater than 1.0200.

(h) In order to ensure that blind performance test samples continue to meet the criteria set forth in paragraph (g) of this section, licensees and other entities shall—

(1) Ensure that all blind performance test sample lots are placed in service by the supplier only after confirmation by an HHS-certified laboratory, and for no more than 6 months;

(2) Ensure that the supplier provides the expiration date for each blind performance test sample to ensure that each sample will have the expected value when it is submitted to and tested by a laboratory; and

(3) At a minimum, require the supplier to check each open lot bi-monthly (*i.e.*, every two months) to ensure that samples remaining in the lot do not fall below 130 percent of the initial cutoff test concentration established by the assay manufacturer. Thus, for example, a lot that was certified by an

HHS-certified laboratory at 155 percent of the manufacturer's assay cutoff level, and was reported by the licensee's or other entity's HHS-certified laboratory to be at or above 130 percent of that standard is acceptable. A test that indicated a result below 130 percent of that standard would be unacceptable. Licensees and other entities shall discard blind performance test samples from any lot that is outside of these parameters and may not use any further samples from that lot.

(i) Licensees and other entities shall ensure that each blind performance test sample is indistinguishable to laboratory personnel from a donor's specimen, as follows:

(1) The licensee or other entity shall submit blind performance test samples to the laboratory using the same channels (*i.e.*, from the licensee's or other entity's collection site or licensee testing facility, as appropriate) through which donors' specimens are sent to the laboratory;

(2) The collector and licensee testing facility personnel, as appropriate, shall use a custody-and-control form, place fictional initials on the specimen bottles' labels/seals, and indicate for the MRO on the MRO's copy that the specimen is a blind performance test sample; and

(3) The licensee or other entity shall ensure that all blind performance test samples include split samples, when the FFD program includes split specimen procedures.

#### § 26.169 Reporting Results.

(a) The HHS-certified laboratory shall report test results to the licensee's or other entity's MRO within 5 business days after receiving the specimen from the licensee or other entity. Before reporting any test result to the MRO, the laboratory's certifying scientist shall certify the result as correct. The report must identify the substances for which testing was performed; the results of the validity and drug tests; the cutoff levels for each; any indications of tampering, adulteration, or substitution that may be present; the specimen identification number assigned by the licensee or